



## **OVERVIEW OF THE ACTION<sup>1</sup>**

1. NeoGenomics expressly denies that any NeoGenomics product or any of its activities fall within the alleged scope of any claim of U.S. Patent Nos. 11,530,454 (the “’454 Patent”) and 11,519,035 (the “’035 Patent”) (collectively, “Asserted Patents”) or otherwise constitute infringement. NeoGenomics admits that the Complaint purports to state an action for infringement of the ‘454 and ’035 Patents. Except as expressly admitted herein, NeoGenomics denies each and every allegation in paragraph 1 of the Complaint.

## **THE PARTIES**

2. NeoGenomics admits that Natera is a corporation organized and existing under the laws of the state of Delaware.

3. Paragraph 3 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 3 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

4. Paragraph 4 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 4 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

5. Paragraph 5 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 5 contains factual allegations, NeoGenomics is without

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<sup>1</sup> For the Court’s convenience, NeoGenomics generally adopts the headings used in Natera’s Complaint. In so doing, NeoGenomics does not admit that the headings are accurate, and reserves the right to contest any statement or characterization set forth under them. To the extent the headings constitute allegations requiring a response, they are denied.

knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

6. Paragraph 6 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 6 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

7. Denied. NeoGenomics specifically denies that it has committed the alleged acts of infringement or that NeoGenomics “used Natera’s patented cfDNA technology.” NeoGenomics further denies that the Asserted Patents claim “patented inventions.”

8. NeoGenomics admits that it is a corporation organized and existing under the laws of the State of Florida. NeoGenomics further admits that it operates laboratories throughout the United States, including in Durham, North Carolina.

9. NeoGenomics admits that it is a corporate affiliate of both Inivata, Inc. and Inivata Ltd. (collectively, “Inivata”). NeoGenomics further admits that it is a wholly owned subsidiary of NeoGenomics, Inc. and that Inivata, Inc. and Inivata Ltd. are wholly owned subsidiaries of NeoGenomics.

10. NeoGenomics admits that it operates under and identifies with the trade name “NeoGenomics” and “NeoGenomics Laboratories.” Except as so admitted, NeoGenomics denies the remaining allegations in paragraph 10.

11. NeoGenomics denies each and every allegation in paragraph 11. NeoGenomics specifically denies that it has used or is using Natera’s patented technology.

## **JURISDICTION AND VENUE**

12. NeoGenomics admits that this Court has subject matter jurisdiction over causes of action for alleged patent infringement pursuant to 28 U.S.C. §§ 1331 and 1338(a).

13. The allegation of personal jurisdiction in paragraph 13 constitutes a legal conclusion that requires no response.

14. The allegation of proper venue in paragraph 14 constitutes a legal conclusion that requires no response.

## **BACKGROUND**

15. Paragraph 15 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 15 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

16. Paragraph 16 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 16 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

17. Paragraph 17 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 17 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

18. Paragraph 18 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 18 contains factual allegations, NeoGenomics is

without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

19. Paragraph 19 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 19 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

20. Paragraph 20 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 20 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

21. Paragraph 21 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 21 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

22. Paragraph 22 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 22 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

23. Paragraph 23 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 23 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

24. Paragraph 24 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 24 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

25. Paragraph 25 of the Complaint contains statements of opinions to which no response is required. To the extent paragraph 25 contains factual allegations, NeoGenomics is without knowledge or information sufficient to form a belief as to the truth of those allegations, and therefore denies each and every allegation in that paragraph.

**Response To Allegations Regarding General Background of the Inventions**

**A. The '454 Patent**

26. NeoGenomics admits that, on its face, the '454 Patent is entitled "Detecting Mutations and Ploidy in Chromosomal Segments," states that it was issued on December 20, 2022, and lists Natera as the assignee. As to the remaining allegations, NeoGenomics is without knowledge or information sufficient form a belief as the truth of the allegations, and therefore denies the remaining allegations in that paragraph.

27. NeoGenomics admits that, on its face, claim 1 of the '454 Patent recites:

A method for preparing a plasma sample of a subject having cancer or suspected of having cancer or useful for detecting one or more single nucleotide variant (SNV) mutations in the plasma sample, the method comprising:

performing whole exome sequencing or whole genome sequencing on a tumor sample of the subject to identify a plurality of tumor-specific SNV mutations;

performing targeted multiplex amplification to amplify 10 to 500 target loci each encompassing a different tumor-specific SNV mutation from cell-free DNA isolated from a plasma sample of the subject or DNA derived therefrom to obtain amplicons having a length of 50-150 bases, wherein the target loci are amplified together in the same reaction volume; and

sequencing the amplicons to obtain sequence reads, and detecting one or more of the tumor-specific SNV mutations present in the cell-free DNA from the sequence reads, wherein the sequencing has a depth of read of at least 50,000 per target locus.

NeoGenomics admits that claim 1 recites “single nucleotide variant (SNV) mutations,” “whole genome sequencing,” and “multiplex amplification.” NeoGenomics denies the remaining allegations in paragraph 27.

28. Paragraph 28 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 28.

29. Paragraph 29 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 29.

## **B. The '035 Patent**

30. NeoGenomics admits that, on its face, the '035 Patent is entitled “Methods for Simultaneous Amplifications of Target Loci,” states that it was issued on December 6, 2022, and lists Natera as the assignee. As to the remaining allegations, NeoGenomics is without knowledge or information sufficient form a belief as the truth of the allegations, and therefore denies the remaining allegations in that paragraph.

31. NeoGenomics admits that, on its face, claim 1 of the '035 Patent recites:

A method for amplifying and sequencing DNA, comprising:

tagging isolated cell free DNA with one or more universal tail adaptors to generate tagged products, wherein the isolated cell-free DNA is isolated from a blood sample collected from a subject who is not a pregnant women;

amplifying the tagged products one or more times to generate final amplification products, wherein one of the amplification steps comprises targeted amplification of a plurality of single nucleotide polymorphism (SNP) loci

in a single reaction volume, wherein one of the amplifying steps introduces a barcode and one or more sequencing tags; and

sequencing the plurality of SNP loci on the cell free DNA by conducting massively parallel sequencing on the final amplification products, wherein the plurality of SNP loci comprises 25-2,000 loci associated with cancer.

NeoGenomics admits that claim 1 recites “amplifying and sequencing,” “targeted amplification of a plurality of single nucleotide polymorphism (SNP) loci,” and “sequencing the plurality of SNP loci” conditions.” NeoGenomics denies the remaining allegations in paragraph 31.

32. Paragraph 32 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 32.

33. Paragraph 33 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 33.

#### **DEFENDANT’S INFRINGING ACTS**

34. Paragraph 34 of the Complaint purports to contain disclaimers and provisos by Natera to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 34.

35. NeoGenomics denies that its products, such as RaDaR, “apply Natera’s patented methods for preparing, amplifying, sequencing, and analyzing cfDNA to detect and monitor genes and genetic mutations associated with a patient’s cancer.” NeoGenomics denies each and every allegation in paragraph 35.

36. Paragraph 36 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 36.



37. Paragraph 37 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 37.

38. NeoGenomics admits that documents purporting to be claim charts for claim 1 of the '454 Patent and claim 1 of the '035 Patent are attached to the Complaint as Exhibits 3–4 with referenced documents contained in Exhibits 5–16. The claim charts and referenced documents contain statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in the claim charts, and further denies that Exhibits 5–16 support the allegations, opinions, and legal conclusions in the claim charts. NeoGenomics denies each and every allegation in paragraph 38.

39. Paragraph 39 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in Exhibit 3 and Exhibit 4. NeoGenomics further denies each and every allegation in paragraph 39.

40. NeoGenomics admits that it “designs, develops, makes and uses, or directs or controls the design, development, make and use of, the RaDaR assay by purposefully directing the activities at its CAP/CLIA-certified laboratory in the Research Triangle Park (RTP) located at 8 Davis Drive, Durham, North Carolina.” NeoGenomics further admits that, “this laboratory is registered to Inivata, Inc., a corporate affiliate of NeoGenomics Laboratories.” NeoGenomics admits that Dr. Siby Sebastian, Ph.D previously served as a director of this laboratory. NeoGenomics further admits that Dr. Siby Sebastian was “the Director of the NeoGenomics CAP/CLIA Clinical Laboratory at the Research Triangle Park (RTP), North Carolina.” NeoGenomics admits that its 2022 Annual Report to shareholders indicated NeoGenomics “ha[s]

a renewed focus on next-generation sequencing (NGS), minimal residual disease (MRD) technology such as RaDaR,<sup>®</sup> MultiOmyx,<sup>™</sup> and data capture and commercialization. Functions under this business include Pharma Services, as it is the tip of the spear for driving innovation in our industry, Informatics (the former Trapelo business), and centralized research and development. By centralizing the R&D function and integrating Inivata, we believe we are now well-positioned to capitalize on the innovation of Inivata while enhancing the development process for new products.”

41. NeoGenomics admits that it performs, or directs or controls the performance of, the RaDaR assay. NeoGenomics further admits that, in its published guide for patients, NeoGenomics Laboratories states that RaDaR testing is “conducted on [a] blood sample in our lab.”

42. NeoGenomics admits that it offers for sale and sells, or directs or controls the offer for sale and sale of, the Accused Assay. NeoGenomics admits that, on March 16, 2023, it clinically launched the RaDaR product for sale in the United States. NeoGenomics also admits that, in its 2022 Annual Report to shareholders, it stated that “[w]e believe NeoGenomics is well-positioned to gain market share with our NGS portfolio products, including Neo Comprehensive – Solid Tumor and Neo Comprehensive – Myeloid Disorders, as well as our RaDaR<sup>®</sup> assay liquid biopsy test for MRD.”

43. NeoGenomics admits that, while RaDaR is ordered through NeoGenomics Laboratories, its insurance reimbursement certifications and approvals, including MolDX, list Inivata as authorized to perform RaDaR tests. NeoGenomics further admits that the request forms for the RaDaR test report that RaDaR may be performed by Inivata. Paragraph 43 otherwise contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 43.

44. Paragraph 44 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 44.

45. NeoGenomics admits that, on July 27, 2023, it announced that RaDaR obtained Medicare coverage for cancer recurrence detection and monitoring in patients with breast cancer, including those with a personal history of high-risk stage II/III HR+/HER2- breast cancer, five or more years from diagnosis who presently do not have evidence of disease.

46. NeoGenomics admits that it had actual knowledge of the '454 Patent since at least as early as December 20, 2022 when Natera filed an infringement lawsuit in the District of Delaware asserting the '454 Patent against two corporate affiliates of NeoGenomics Laboratories, Inc.: Inivata, Inc., and Inivata, Ltd.

47. NeoGenomics admits that it had actual knowledge of the '035 Patent since at least as early as the date of this Complaint.

48. NeoGenomics denies that it has “made extensive unauthorized use of Natera’s patented technology.” The remainder of paragraph 48 of the Complaint contains statements of opinion and legal conclusions to which no response is required. To the extent a response is required, NeoGenomics denies each and every allegation in paragraph 48.

**COUNT I: DIRECT INFRINGEMENT OF U.S. PATENT NO. 11,530,454**

49. NeoGenomics incorporates and restates by reference its responses to paragraphs 1–48 of the Complaint as though fully set forth herein.

50. NeoGenomics lacks sufficient knowledge or information to form a belief as to the truth of the allegations set forth in paragraph 50 and on that basis denies them.

51. NeoGenomics denies each and every allegation in paragraph 51 of the Complaint.

52. NeoGenomics denies each and every allegation in paragraph 52 of the Complaint.

53. NeoGenomics denies each and every allegation in paragraph 53 of the Complaint.

**COUNT II: DIRECT INFRINGEMENT OF U.S. PATENT NO. 11,519,035**

54. NeoGenomics incorporates and restates by reference its responses to paragraphs 1–48 of the Complaint as though fully set forth herein.

55. NeoGenomics lacks sufficient knowledge or information to form a belief as to the truth of the allegations set forth in paragraph 55 and on that basis denies them.

56. NeoGenomics denies each and every allegation in paragraph 56 of the Complaint.

57. NeoGenomics denies each and every allegation in paragraph 57 of the Complaint.

58. NeoGenomics denies each and every allegation in paragraph 58 of the Complaint.

**COUNT III: INDIRECT INFRINGEMENT OF U.S. PATENT NO. 11,530,454**

59. NeoGenomics incorporates and restates by reference its responses to paragraphs 1–48 of the Complaint as though fully set forth herein.

60. NeoGenomics denies each and every allegation in paragraph 60 of the Complaint.

61. NeoGenomics denies each and every allegation in paragraph 61 of the Complaint.

62. NeoGenomics denies each and every allegation in paragraph 62 of the Complaint.

**COUNT IV: INDIRECT INFRINGEMENT OF U.S. PATENT NO. 11,519,035**

63. NeoGenomics incorporates and restates by reference its responses to paragraphs 1–48 of the Complaint as though fully set forth herein.

64. NeoGenomics denies each and every allegation in paragraph 64 of the Complaint.

65. NeoGenomics denies each and every allegation in paragraph 65 of the Complaint.

66. NeoGenomics denies each and every allegation in paragraph 66 of the Complaint.

**COUNT V: WILLFULL INFRINGEMENT OF U.S. PATENT NO. 11,530,454**

67. NeoGenomics incorporates and restates by reference its responses to paragraphs 1–48 of the Complaint as though fully set forth herein.

68. NeoGenomics denies each and every allegation in paragraph 68 of the Complaint.

69. NeoGenomics denies each and every allegation in paragraph 69 of the Complaint.

70. NeoGenomics denies each and every allegation in paragraph 70 of the Complaint.

**COUNT VI: WILLFULL INFRINGEMENT OF U.S. PATENT NO. 11,519,035**

71. NeoGenomics incorporates and restates by reference its responses to paragraphs 1–48 of the Complaint as though fully set forth herein.

72. NeoGenomics denies each and every allegation in paragraph 72 of the Complaint.

73. NeoGenomics denies each and every allegation in paragraph 73 of the Complaint.

74. NeoGenomics denies each and every allegation in paragraph 74 of the Complaint.

**PRAYER FOR RELIEF**

NeoGenomics denies that Natera is entitled to any relief whatsoever, including the relief requested in the Complaint, from either NeoGenomics or the Court. Natera’s prayer for relief should be denied in its entirety.

**AFFIRMATIVE DEFENSES**

NeoGenomics hereby sets forth defenses to Natera’s Complaint in order to place Natera on notice regarding applicable defenses. By listing any matter as a defense herein, NeoGenomics does not assume the burden of proving any matter upon which Natera, or any other party, bears the burden of proof under applicable law.

### **FIRST DEFENSE – NON-INFRINGEMENT**

1. NeoGenomics has not infringed, and is not infringing directly, indirectly, willfully, or in any other manner any valid and enforceable claim of the Asserted Patents, either literally or under the doctrine of equivalents.

### **SECOND DEFENSE – INVALIDITY**

2. The asserted claims of the Asserted Patents are invalid for failing to comply with one or more of the requirements for patentability under, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112 *et seq.*, and the rules, regulations, and laws pertaining to those provisions, including the application provisions of Title 37 of the Code of Federal Regulations.

### **THIRD DEFENSE – FAILURE TO STATE A CLAIM**

3. Natera's Complaint, in whole or in part, fails to state a claim upon which relief may be granted.

4. As an example, Natera's Complaint fails to state a claim upon which relief may be granted because the claims of the Asserted Patents are invalid for failing to comply with one or more of the requirements for patentability under, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, 112 *et seq.* as set forth below in NeoGenomics' Counterclaims.

### **FOURTH DEFENSE – PROSECUTION HISTORY ESTOPPEL/DISCLAIMER**

5. Natera is estopped from construing the claims of the Asserted Patents to cover or include, either literally or by application of the doctrine of equivalents, products manufactured, used, imported, sold, or offered for sale by NeoGenomics or methods used by NeoGenomics because of amendments, admissions, representations, or statements made before the USPTO during prosecution of the applications leading to the issuance of the Asserted Patents or

applications related thereto, because of disclosures or language in the specifications of the Asserted Patents, and/or because of limitations in the claims of the Asserted Patents.

**FIFTH DEFENSE – LIMITATIONS ON RECOVERY**

6. Natera's claims for damages and other remedies are limited by 35 U.S.C. §§ 287 and/or 288. Natera is barred by 35 U.S.C. § 288 from recovering costs associated with this action.

**SIXTH DEFENSE – ADEQUATE REMEDY AT LAW**

7. Natera is not entitled to injunctive relief against NeoGenomics because Natera is not likely to succeed on the merits, any alleged injury is neither immediate nor irreparable, there is an adequate remedy at law for any alleged injury, the balance of hardships and equities does not favor an injunction, and the public interest would be disserved by an injunction. Accordingly, Natera is not entitled to injunctive relief even if it were able to establish liability.

**SEVENTH DEFENSE – NO EXCEPTIONAL CASE**

8. NeoGenomics has not engaged in any conduct that would make this an exceptional case or that would entitle Natera to an award of attorneys' fees.

**EIGHTH DEFENSE – ACTIONS OF OTHERS**

9. On information and belief, Natera's claims are barred, in whole or in part, because NeoGenomics is not liable for the acts of others over whom it has no control.

**NINTH DEFENSE – CLAIM PRECLUSION**

10. Natera is barred from bringing this action, in whole or in part, pursuant to the doctrine of claim preclusion.

11. On January 20, 2021, Natera filed a complaint in the District Court for the District of Delaware against Inivata, Inc. and Inivata Ltd. alleging infringement of U.S. Patent Nos. 10,262,755 and 10,597,709. *Natera, Inc. v. Inivata, Inc.*, C.A. No. 1:12-cv-00056-UNA, D.I. 1.

On December 20, 2022, Natera filed a complaint in the District Court for the District of Delaware against Inivata, Inc. and Inivata Ltd. alleging infringement of the '454 Patent. *Natera, Inc. v. Inivata, Inc.*, C.A. No. 1:22-cv-01609-UNA, D.I. 1. Natera is barred from bringing this action, in whole or part, based on the aforementioned Delaware actions, which were consolidated on January 26, 2023.

#### **TENTH DEFENSE – INEQUITABLE CONDUCT**

12. The '454 Patent is unenforceable due to Natera's inequitable conduct during the prosecution of the '454 Patent.

13. The '454 Patent claims the use of "whole exome" or "whole genome" sequencing of a "tumor sample" followed by "sequencing the amplicons" obtained by amplifying "10 to 500 target loci" in "cell-free DNA isolated from a plasma sample."

14. While the '454 Patent fails to adequately describe the claims, to the extent the '454 Patent includes any reference to an approach based on the use of "whole exome" or "whole genome sequencing," such disclosure appears solely in Example 13.

15. Example 13, however, describes a series of experiments that were conceived of not by the named inventors, but by researchers at University College London, including at least Mariam Jamal-Hanjani, who described the work that appears in Example 13 in her doctoral dissertation.

16. This is clear from, for example, the figures and lists of genes referred to in Example 13, which are identical to those set forth in the doctoral dissertation of Mariam Jamal-Hanjani.

17. On information and belief, the named Natera inventors and the individuals involved in prosecuting the '454 Patent (including, without limitation, Nishita Doshi, Tianran Yan, Luke



Burton, and Limin Zheng) were aware that the disclosure set forth in Example 13 of the '454 patent was conceived of and performed by researchers at University College London.

18. These individuals were aware that researchers had conceived of and performed the work in Example 13 because Natera had been engaged in a collaboration with researchers at University College London related to precisely this work and, on information and belief, were in regular communication regarding research and development activities.

19. Yet, despite being aware that researchers at University College London had conceived of and performed the work in Example 13, the Natera inventors and patent prosecution team included Example 13 in their application that became the '454 patent and then drafted claims that rely upon the subject matter of Example 13 without identifying any researchers from University College London as inventors.<sup>2</sup>

20. The Natera inventors and patent prosecution team omitted researchers from University College London as inventors because they wished to misappropriate the subject matter of Example 13 and be free to draft related claims and enforce such claims without being encumbered by University College London, which, on information and belief, Natera no longer collaborates with after having had a high-profile falling out with Charles Swanton, a leading oncology researcher who led the collaboration with Natera.

21. Natera's misrepresentation of inventors to the Patent Office was highly material. Title 35 U.S.C. § 115 provides that "An application for patent ... shall include, or be amended to

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<sup>2</sup> The content in Example 13 is material, which is supported by the fact that Natera specifically relied on Example 13 for support during the prosecution of at least two related patent applications. *See, e.g.*, Ex. 1 at 7 (alleging that then-pending claims 1, 16-17, 20-23 and 25 are supported by Example 13 (i.e., paragraph 0863 of the published application (US2018/0320239))); Ex. 2 at 1 (asserting that then-pending claims 1, 2, 4-8, and 10-11 derive basis from Example 13).

include, the name of the inventor for any invention claimed in the application.” Section 115 further states, “Except as otherwise provided in this section, each individual who is the inventor or a joint inventor of a claimed invention in an application for patent shall execute an oath or declaration in connection with the application.” The Manual of Patent Examining Procedure (“MPEP”) thus instructs examiners to reject applications with improper inventorship. *See* MPEP § 2137.01 (explaining that “U.S. patent law” requires “naming of the actual inventors”). The MPEP explains that “if a determination is made that the inventive entity named in a U.S. application is not correct . . . a rejection should be made on this basis.” *Id.* “As a critical requirement for obtaining a patent, inventorship is material.” *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315, 1321 (Fed. Cir. 2000).

22. Had the Examiner been apprised of the fact that the work in Example 13 was conceived of and performed by researchers at University College London, the Examiner would have required correction to the inventorship group and would not have issued the patent without such a correction.

#### **ELEVENTH DEFENSE – UNCLEAN HANDS**

23. Natera’s patent infringement claims are barred in whole or in part under the doctrine of unclean hands.

24. Based on the business misconduct set forth in connection with NeoGenomics’ Tenth Defense related to inequitable conduct, Natera has engaged in unclean hands with respect to the ’454 Patent such that it is now unenforceable.

#### **NEOGENOMICS’ COUNTERCLAIMS AGAINST NATERA**

In support of its Counterclaims against Natera, NeoGenomics alleges as follows:

### **NATURE OF THE ACTION**

1. In response to Natera's allegations in the Complaint, NeoGenomics seeks a declaratory judgment that it has not infringed the Asserted Patents, that the Asserted Patents are invalid, and that the '454 Patent is unenforceable under the Patent Laws of the United States, 35 U.S.C. § 271 *et seq.*

### **THE PARTIES**

2. Natera is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 201 Industrial Road, Suite 410, San Carlos, California 94070.

3. NeoGenomics is a corporation organized and existing under the laws of the State of Florida, with its principal place of business at 9490 NeoGenomics Way, Fort Myers, FL 33912.

### **JURISDICTION AND VENUE**

4. The Court has subject matter jurisdiction over NeoGenomics' declaratory judgment counterclaims pursuant to 28 U.S.C. §§ 2201 and 2202.

5. The Court has personal jurisdiction over Natera because Natera consented to jurisdiction in this District by filing its Complaint in this action.

6. To the extent that venue is proper in the underlying patent infringement action, venue is also proper with respect to NeoGenomics' Counterclaims pursuant to 28 U.S.C. §§ 1391 and 1400(b) and because Natera consented to this venue by filing its Complaint in this action.

### **FIRST COUNT**

#### **(Declaration of Non-Infringement of U.S. Patent 11,530,454)**

7. NeoGenomics incorporates by reference and restates the preceding paragraphs 1-6 of its Counterclaims as though fully set therein.

8. Natera has brought an action asserting the '454 Patent against NeoGenomics and has alleged that it is the legal owner of the '454 Patent.

9. Natera has alleged and continues to allege that NeoGenomics has directly, indirectly, and willfully infringed and continues to directly, indirectly, and willfully infringe one or more claims of the '454 Patent.

10. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and exists between Natera and NeoGenomics concerning whether NeoGenomics has infringed and is infringing any valid and enforceable claim of the '454 Patent.

11. NeoGenomics hereby seeks a declaration that NeoGenomics has not infringed and is not infringing any valid and enforceable claim of the '454 Patent.

12. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

## **SECOND COUNT**

### **(Declaration of Non-Infringement of U.S. Patent 11,519,035)**

13. NeoGenomics incorporates by reference and restates the preceding paragraphs 1-12 of its Counterclaims as though fully set therein.

14. Natera has brought an action asserting the '035 Patent against NeoGenomics and has alleged that it is the legal owner of the '035 Patent.

15. Natera has alleged and continues to allege that NeoGenomics has directly, indirectly, and willfully infringed and continues to directly, indirectly, and willfully infringe one or more claims of the '035 Patent.

16. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and exists between Natera and NeoGenomics concerning whether NeoGenomics has infringed and is infringing any valid and enforceable claim of the '035 Patent.

17. NeoGenomics hereby seeks a declaration that NeoGenomics has not infringed and is not infringing any valid and enforceable claim of the '035 Patent.

18. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

### **THIRD COUNT**

#### **(Declaration of Invalidity of U.S. Patent 11,530,454)**

19. NeoGenomics incorporates by reference and restates the preceding paragraphs 1-18 of its Counterclaims as though fully set therein.

20. Natera has brought an action asserting the '454 Patent against NeoGenomics and has alleged that it is the legal owner of the '454 Patent.

21. Natera has alleged and continues to allege that NeoGenomics has directly, indirectly, and willfully infringed and continues to directly, indirectly, and willfully infringe one or more claims of the '454 Patent.

22. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and exists between Natera and NeoGenomics concerning whether NeoGenomics has infringed and is infringing any valid and enforceable claim of the '454 Patent.

23. The claims of the '454 Patent are invalid for failing to comply with the provisions of the Patent Laws, Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, and/or the rules, regulations, and laws pertaining thereof.

24. NeoGenomics incorporates by reference and restates the preceding paragraph 2 of NeoGenomics' Second Affirmative Defense of Invalidity as though fully set forth herein.

25. NeoGenomics hereby seeks a declaration that the claims of the '454 Patent are invalid.

26. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

#### **FOURTH COUNT**

##### **(Declaration of Invalidity of U.S. Patent 11,519,035)**

27. NeoGenomics incorporates by reference and restates the preceding paragraphs 1-26 of its Counterclaims as though fully set therein.

28. Natera has brought an action asserting the '035 Patent against NeoGenomics and has alleged that it is the legal owner of the '035 Patent.

29. Natera has alleged and continues to allege that NeoGenomics has directly, indirectly, and willfully infringed and continues to directly, indirectly, and willfully infringe one or more claims of the '035 Patent.

30. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and exists between Natera and NeoGenomics concerning whether NeoGenomics has infringed and is infringing any valid and enforceable claim of the '035 Patent.

31. The claims of the '035 Patent are invalid for failing to comply with the provisions of the Patent Laws, Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, and/or the rules, regulations, and laws pertaining thereof.

32. NeoGenomics incorporates by reference and restates the preceding paragraph 2 of NeoGenomics' Second Affirmative Defense of Invalidity as though fully set forth herein.

33. NeoGenomics hereby seeks a declaration that the claims of the '035 Patent are invalid.

34. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

### **FIFTH COUNT**

#### **(Declaration of Unenforceability of U.S. Patent 11,530,454)**

35. NeoGenomics incorporates by reference and restates the preceding paragraphs 1-34 of its Counterclaims as though fully set therein.

36. Natera has brought an action asserting the '454 Patent against NeoGenomics and has alleged that it is the legal owner of the '454 Patent.

37. Natera has alleged and continues to allege that NeoGenomics has directly, indirectly, and willfully infringed and continues to directly, indirectly, and willfully infringe one or more claims of the '454 Patent.

38. An actual controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, has arisen and exists between Natera and NeoGenomics concerning whether NeoGenomics has infringed and is infringing any valid and enforceable claim of the '454 Patent.

39. NeoGenomics incorporates by reference and restates the preceding paragraphs 12–24 of NeoGenomics' Tenth and Eleventh Affirmative Defenses of Inequitable Conduct and Unclean Hands as though fully set forth herein.

40. NeoGenomics hereby seeks a declaration that the claims of the '454 Patent are unenforceable due to inequitable conduct and unclean hands.

41. A judicial declaration is necessary and appropriate at this time so that the parties may proceed in accordance with their respective rights and duties determined by the Court.

**RESERVATION OF RIGHTS**

42. NeoGenomics expressly reserves the right to assert any additional defenses or counterclaims that may now exist or in the future may be available based on discovery and further factual investigation in this case.

**DEMAND FOR JURY TRIAL**

43. NeoGenomics hereby demands a trial by jury of all issues so triable in this action.

**REQUEST FOR RELIEF**

WHEREFORE, having fully answered the Complaint and having asserted Affirmative Defenses, and Counterclaims, NeoGenomics respectfully requests the following relief:

A. That this Court enter judgment on Natera's Complaint and NeoGenomics' Counterclaims in favor of NeoGenomics, against Natera, with Natera being awarded no relief of any kind in this action;

B. That this Court enter judgment and/or declarations that NeoGenomics does not infringe the Asserted Patents, that the Asserted Patents are invalid, and that the '454 Patent is unenforceable;

C. That this Court enter a judgment declaring this case exceptional under 35 U.S.C. § 285 and awarding NeoGenomics its attorneys' fees and prejudgment and post-judgment interest;

D. That this Court award NeoGenomics all of its costs of this action; and

E. That this Court grant such other and further relief as the Court shall deem just and proper.



Dated: September 11, 2023

Respectfully submitted,

/s/ John F. Morrow, Jr.  
Attorney (N.C. Bar No. 23382)  
WOMBLE BOND DICKINSON (US) LLP  
One West Fourth Street  
Winston-Salem, North Carolina 27101  
Telephone: (336) 721-3584  
Email: john.morrow@wbd-us.com

Edward R. Reines\*  
Derek C. Walter\*  
WEIL, GOTSHAL & MANGES LLP  
201 Redwood Shores Parkway  
Redwood Shores, CA 94065  
Tel: (650) 802-3000  
Fax: (650) 802-3100  
edward.reines@weil.com  
derek.walter@weil.com

*Counsel for Defendant NeoGenomics  
Laboratories, Inc.*

*\* Special Appearance Under Local Rule 83.1(d)*